

**REMARKS**

The Advisory Office Action dated February 2, 2005 has been carefully reviewed and the foregoing remarks are made in response thereto. Applicants again acknowledge the efforts of the Examiner's supervisor in discussing the merits of the rejection on multiple occasions. The amendments contained herein are in response to those discussions. In view of the above claim amendments and following remarks, Applicant respectfully requests reconsideration and reexamination of this application and timely allowance of the pending claims.

By this Amendment, claims 97, 112, 115, 119 and 122 to 124 have been amended. Applicants submit that no new prohibited matter has been introduced by the amendments and that while written support for the amendments can be found throughout the specification, examples of specific support for the claim amendments can be found in Figure 1 and in Table 7 on page 32. Specific written support for claims 112 and 119 can be found on page 31.

**Summary of the Advisory Office Action**

The Examiner refused to enter the after-final amendment filed on January 21, 2005 on the grounds that the amendments to the claims raised new issues. Specifically, the Examiner indicated that the amendments raised an issue under 35 U.S.C. 112 (second paragraph) with regard to claim 101 and under 35 U.S.C. 112 (first paragraph) with regard to claims 111 to 114 and 118 to 121.

**Response to the Advisory Office Action**

Applicants disagree with the Examiner because the amendments to the claims put the application in better condition for appeal by obviating the rejection of claims 97 and 115 as evidenced by the statement by the Examiner in the Advisory Action that such claims were allowable. Applicants bring to the attention of the Examiner that any amendment which puts the claims in better condition for appeal may be entered by the Examiner (see MPEP 714.12).

Nonetheless, and solely for the purpose of advancing prosecution, Applicants have amended these claims to address any issues raised by the Examiner in the Advisory Action. With regard to claim 101, Applicants have cancelled this claim without acquiescing to the merits of any rejection by the Examiner and therefore submit that the issue raised by the Examiner is moot.

With regard to claims 111 to 114 and 118 to 121, Applicants are particularly concerned about the issues raised by the Examiner because these claims have never been amended since their first presentation

and the same limitation appears in the allowable subject matter in the corresponding independent claims 97 and 115 (*e.g.*, at least one female individual with a family history which indicates a predisposition to breast cancer). It is unclear to the Applicants how the subject matter in these claims can suddenly be considered new matter when these claims were not amended at any time during prosecution. Nonetheless, and solely for the purpose of advancing prosecution, Applicants have amended or cancelled these claims to address any issues raised by the Examiner in the Advisory Action.

#### **Summary of the Final Office Action**

1. The restriction response was made final but claims 122 to 124 were rejoined with the elected claims in view of amendments to these claims.
2. The priority information in the specification was objected to by the Examiner.
3. Claims 97 to 101, 103 and 105 to 124 were rejected under 35 U.S.C. 112 (first paragraph) for purportedly not being enabled by the specification.
4. Claims 97 to 101, 103 and 105 to 124 were rejected under 35 U.S.C. 112 (second paragraph) for purportedly being indefinite.
5. Claims 97 to 101, 103 and 105 to 124 were rejected under the judicially created doctrine of obviousness type double patenting.

#### **Objection to the Priority Information in the Specification**

Applicants have amended the priority information to clarify the relationship of the present application of being a continuation-in-part of two separate applications (*i.e.*, U.S. Applications 08/905,772 and 09/084,471). Applicants have also amended the priority information to update the status of each of the priority applications where applicable. In view of these amendments, Applicants request withdrawal of the objection.

#### **Rejection under 35 U.S.C. 112 (first paragraph)**

Claims 97 to 101, 103 and 105 to 124 were rejected under 35 U.S.C. 112 (first paragraph) for purportedly not being enabled by the specification. Applicants appreciate the input from the Examiner in multiple telephone discussions regarding claim language which is enabled by the specification. In view of these discussions, but without acquiescing to the merits of the rejection, Applicants have amended the claims such that they are directed to determining the presence of an omi1 haplotype by detecting the

presence of each of the recited variations in the nucleotide or amino acid sequence. As further support that the subject matter of amended claims is enabled by the specification, Applicants bring to the attention of the Examiner the statements in the previous Office Action indicating that such subject matter is enabled by the specification (see Office Action dated April 21, 2004 at page 3). In view of these claim amendments, Applicants submit that the rejection is moot and request withdrawal of the rejection.

**Rejection under 35 U.S.C. 112 (second paragraph)**

Claims 97 to 101, 103 and 105 to 124 were rejected under 35 U.S.C. 112 (second paragraph) for purportedly being indefinite. The Examiner purports that it is unclear how the presence of a variation indicates the haplotype. Without acquiescing to the merits of the rejection, Applicants have amended these claims to recite distinct variations at defined positions which indicate a specified haplotype (*i.e.*, om1). In view of these claim amendments, Applicants submit that the rejection is moot and request withdrawal of the rejection.

**Obviousness-type Double Patenting Rejections**

Claims 97 to 101, 103 and 105 to 124 were rejected under the judicially created doctrine of obviousness type double patenting. Applicants attach a terminal disclaimer which disclaims any patent term beyond that of U.S. Patents 5,750,400 or 5,654,155. In view of the terminal disclaimer, Applicants submit that the rejection is moot and request its withdrawal.

**Conclusion**

The foregoing remarks are being made to place the application in better condition for appeal. Applicant respectfully requests reconsideration and entry of the amendments. A favorable action is awaited. Should the Examiner find that an interview would be helpful to further prosecution of this application, she is invited to telephone the undersigned at her convenience.

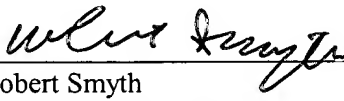
If there are any fees due in connection with the filing of this amendment, please charge the fees to our Deposit Account No. 50-310. If a fee is required for an extension of time under 37 C.F.R. 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

**Except** for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under

37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **constructive petition for extension of time** in accordance with 37 C.F.R. 1.136(a)(3).

Dated: **February 22, 2004**  
Morgan, Lewis & Bockius LLP  
Customer No. **09629**  
1111 Pennsylvania Ave., N.W.  
Washington, D.C. 20004  
202-739-3000

Respectfully submitted  
**Morgan, Lewis & Bockius LLP**

  
Robert Smyth  
Registration No. 50,801